BAYLOR UNIVERSITY MEDICAL CENTER
An affiliate of the Baylor Health Care System

August 16, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

RE: *Draft HCV Guidance Document – Dated June 1999*
Dockets Management Brach (HFA-305)

Dear Sir/Madam:

I strongly request that any further extension of HCV lookback to the 1.0 test. and other measures expressed for comment, in your most recent document. be brought to an immediate halt or at least delayed until the findings of the current HCV 2.0 lookback can be evaluated. As a medical scientist I firmly believe that good health care directives should be based on. factual knowledge, observations and ethics and be devoid of all emotional or political motivations.

Permit me to inform you of some of the findings pertaining to the 2.0 HCV lookback that we have recently completed in our Hospital Health Care System.'.

1. All the blood components' unit numbers received from Blood Centers for recipient identification were found, researched and evaluated for further action.

2. Sixty-seven (67) per cent of the lookback recipients had died.

3. Seventy-seven (77) per cent of patients, required to be notified in the lookback, tested HCV negative.

4. Tivelve (12) per cent of patients notified in the lookback tested positive before transfusion (we had stored pre-transfusion samples dating back to August 1989).

5. Eleven (11) per cent of patients notified tested HCV positive after transfusion and that could have been infected by transfusion. We know that 25% of these were transfused prior to HCV 1.0 testing. Hence, this leaves us with a total of only ten (10) patients who could have been infected after first generation HCV testing had been instituted.

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6. There were no HCV positive recipients who received second generation HCV 2.0 tested blood,

My conclusions are as follows:

1. In our health care system an ertensive and expensive effort was required to find a total of thirteen (13) individuals (among over 60,000 patients transfused) who may have been infected by transfusion. Three (3) of these were transfused before HCV testing became available in 1990.

2. It can be calculated that more blood recipients have been infected and missed by the current method of "targeted" lookback since not all donors have returned to donate since HCV testing was first initiated in 1990.

3. We succeeded in disrupting (some severely) the lives of well over 100 recipients who tested negative for HCV after transfusion.

4. Current donor screening techniques, and HCV testing, appear to be very successful in eliminating HCV infected donors.

5. At this time it would appear that, on balance, 1.0 HCV lookback is not justified. Also it is clear that a general lookback would be far more effective than a transfusion-targeted lookback for. finding HCV infected individuals;

Again, I respectfully urge the guiding committee to evaluate the findings of the current HCV 2.0 lookback program before proceeding with any further regulations that may not. be in the best interest of our patients or health care system. These findings, when available, should form the basis for a consensus conference on this matter.

Yours sincerely,

A. J. Marengo-Rowe, M.D.
Director of Special Hematology and Transfusion Service

AJM-R/lc

A. J. Marengo-Rowe, M.D.

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